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Smith & Nephew Richards Inc.
Reflection Dual Dimension Shell
[510(k) Notification]
Summary of Safety and Effectiveness

K960094

Intended Use

The indications for use include cemented or uncemented total hip arthroplasty for rheumatoid arthritis; osteoarthritis; post-traumatic arthritis; avascular necrosis; femoral neck fractures; osteomyelitis; fracture-dislocation of the hip; and unsuccessful cup arthroplasty, endoprosthesis, femoral osteotomy, or girdlestone resection.

Modifications that do not significantly affect safety and effectiveness.

The outer diameter of The Reflection Dual Dimension Shell has been modified to include an area with a larger diameter. This feature is a peripheral enhancement to the rim of the cup for improved press fit stability. The shell will be available in a no holed version (one apex hole for shell insertion) and a 3-holed version for some adjunctive screw fixations. In addition to the similarities to the previous Reflection Acetabular Component, The Dual Dimension Shell is similar to several shells currently marketed by other companies, The DePuy Duraloc and the Osteonics PSL shells. Since this modification is only to the outer geometry and the internal geometry and the locking mechanism remain the same as the previous Reflection Acetabular Component.

Materials

The acetabular shell is Titanium 6 Aluminum 4 Vanadium Alloy (ISO 5832/III) with a coating of commercial pure (C.P.) titanium beads (ASTM F67).

Substantial Equivalence Information

The legally marketed devices with which the subject device is to be compared for the determination of substantial equivalency.

Features	Reflection D.D.	Osteonics PSL	DePuy Duraloc
Shell Material	Titanium	Titanium	Titanium
Porous Surface	Sintered Beads (rough surface)	Sintered Beads (smooth surface)	Sintered Beads (rough surface)
Shell Geometry	Low Profile (-2mm) with peripheral build-up	Low Profile (-1mm) with peripheral build-up	Low Profile (-3mm)
Shell Options	No holes, Three holes	No holes, Five holes	No holes, 3 holes, 3 spikes, 12 holes
Adjunctive Fixation	Screws	Screws	Screws and fixed spikes
Liner Overhang	Neutral and 20 degree	Neutral, 10, and 20 degree	Neutral, 10, and 15 degree
Polished Inner Surface	Yes	No	Yes (Sector Cup only)